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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,175	10/31/2003	John R. Bianchi	4002-3441	1020
52196 7590 03/19/2007 KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER PRONE, CHRISTOPHER D	
			ART UNIT 3738	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/19/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,175	BIANCHI ET AL.	
	Examiner	Art Unit	
	Christopher D. Prone	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-135 and 249-361 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-135 and 249-361 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Specification

The amendment filed 12/17/04 and the amendment files on 12/8/06 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: "each of dowels 500 are illustrated as having a width less than approximately one-half of the Width of the adjacent vertebral body. Applicant is referred to MPEP 2125, which states:

PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int '1*, 222 F.3d 951, 956, 55 USPQ 2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. "(It is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.")). However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. In *re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977) ("We disagree with the Solicitor's conclusion, reached by a comparison of the relative dimensions of appellant's and Bauer's drawing figures, that Bauer clearly points to the use of a chime length of roughly 1/2 to 1 inch for a whiskey barrel. This ignores the fact that Bauer does not disclose that his drawings are to scale. However, we agree with the Solicitor that Bauer's teaching that whiskey losses are influenced by the distance the liquor needs to traverse the pores of the wood' (albeit in reference to the thickness of the barrelhead)'

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would have suggested the desirability of an increased chime length to one of ordinary skill in the art bent on further reducing whiskey.

Applicant is therefore required **to cancel** the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 72-134 and 249-371 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular in claims 72, 91 and 111 applicant claims the limitations of "...said upper and lower portions being non-arcuate along at least a portion of the length of the implant...". The opposed upper and lower surfaces of applicants implants are not non-arcuate they are described as being flattened. The term non-arcuate is not been defined the same as being flattened. The terms are similar however contrary to the applicant's belief an object may be both flattened and arcuate. An example is a road that is flattened in respect to elevation, but curves to the left or right therefore being a flattened arcuate surface. Applicant is

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encouraged to utilize the terminology in the specification, which is "flattened", which is differently defined than non-arcuate.

Applicant further claims a range of "...less than approximately one-half of the width of the adjacent vertebral bodies" and this range constitutes new matter. The applicant argues this rejection and the above objection to the specification relying on figure 6 for support. The applicant states that it is clear from these figures that the maximum width of the implant is less than half the width of the adjacent vertebral body. However this is not clear because it would be possible to place larger implants in the space that would overlap allowing for a width greater than half of the vertebral bodies width. The drawing shows an example of a possible width but does not show a maximum width by any means.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 72-90, 134, 135, and 264-361 are rejected under 35 U.S.C. 102(e) as being anticipated by Paul et al (6,258,125).

With respect to claims 50 and 77, Paul et al disclose an interbody spinal implant (10, 70) made of bone composite material, the implant comprising a leading end (28) for insertion first into the disc space, a trailing end (26) opposite the leading end, the implant having a length along a mid longitudinal axis of the implant from the leading end to the trailing end; opposed upper and lower portions (14,16) between the leading end and the trailing end adapted to be placed within the disc space to contact and support the adjacent vertebral bodies, the upper and lower portions being non-arcuate along at least a portion of the length of the implant', an interior side (18), an exterior side (20) opposite the interior side, and a maximum width there between, the maximum width of the implant being less than approximately one-half of the width of the adjacent vertebral bodies into which the implant is adapted to be inserted, the interior and exterior sides connecting the upper and lower portions and the leading and trailing ends, the leading end (28) having a having a generally straight portion; as best seen in FIG.9, from side to side, the interior side forming a corner with the generally straight portion of the leading end; as best seen in FIG.9, the interior side (8) adapted to be oriented toward an interior side of another implant when inserted within the disc space, as best seen in Fig.9; the implant being manufactured from a bone composite material', as set forth in column 3, lines 25-30, the interior side of the implant including a recess so that when the implant is placed side by side another implant having an interior side including a recess a passage (72) is formed adapted to hold bone growth promoting material for permitting for the growth of bone from vertebral body to vertebral body through the passage, as set forth in column 5, lines 8-23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 91-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (6,258, 125) in view of Boyle et al. (6,530,955).

It is noted that Paul teach all the limitations, except for an implant manufactured from a bone ring obtained from a long bone having a medullary canal and wherein the implant including 40% of the bone ring; as claimed by applicant. However, in a similar art, Boyle evidence the use of an intervertebral C-shaped implant manufactured from a bone ring obtained from a long bone having a medullary canal or any biocompatible material so that fusion of the implant and adjoining vertebrae will occur more quickly.

Therefore, given the teaching of Boyle, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the composite material of the implant of Paul et al with the bone ring of Boyle so that fusion of the implant and adjoining vertebrae will occur more quickly.

Response to Arguments

Applicant's arguments with respect to claims 72-371 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738


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